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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,720	09/14/2001	Wolfgang Daum	MRI-T108	7606
23557	7590	11/17/2005	EXAMINER	
SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			FOREMAN, JONATHAN M	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

TWCh

<b>Office Action Summary</b>	<b>Application No.</b> 09/954,720	<b>Applicant(s)</b> DAUM ET AL.	
	<b>Examiner</b> Jonathan ML Foreman	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 August 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

New grounds of rejection are contained within this Office Action. Accordingly this action has been made Non-Final.

#### ***Drawings/Specification***

1. The amendment filed 8/8/05 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: In regards to the Drawings, each of the newly submitted drawings is considered to introduce new matter. At a minimum, each drawing shows a tapered distal section that was previously not disclosed in the Specification. Additionally, Figures 2A and 2B appear to show two different tapering connections utilizing glue that was not previously disclosed in the Specification; Figure 3 shows a rounded portion of the main part extending into the distal part that was previously undisclosed; and Figure 4 shows a tapered connection between the main part and the distal part. In regards to the written description, the replaced paragraph at page 2, line 16 is considered to introduce new matter in that it describes figures containing new matter. The paragraph at page 2, line 35 introduces new matter in that it makes reference to Figure 5. The paragraph at page 3, line 1 introduces new matter in that it makes reference to Figures 2A, 2B, 3 and 4. Additionally, the paragraph at page 3, line 1 introduces for the first time that "crimps" can be used to connect the distal part to the main part. The last paragraph on page 3 introduces new matter in that it refers to a Crimp, Shrink-tube, core and glue in figures that introduce new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

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### ***Drawings***

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the pinched distal part, the shrinkdown plastic tubing connection and the core within the center of the main part must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 3, 4, 7, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S.

Patent No. 5,596,996 to Johanson et al.

In regards to claims 1, 3, 4, 7, 9 and 10, Johanson et al. discloses an MRI compatible device for guiding catheters having a metallic wire distal part (45) and an MRI-inert plastics main part (Col. 3, lines 61 – 65; Col. 4, lines 27 - 36). The distal part and the main part are glued together (Col. 5, line 24). The main part comprises a core comprising an insulant material (Col. 4, lines 37 – 42). The main part comprises an artificial material selected from the group of polypropylene, polyethylene, polyetherimides, and polyetheretherketone (Col. 4, lines 37 – 42).

5. Claims 1 - 5 and 7 - 10 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S.

Patent No. 6,375,629 to Muni et al.

In regards to claims 1 - 5 and 7 - 10, Muni et al. discloses an MRI compatible device for guiding catheters having a metallic wire distal part (26) comprising nickel titanium or stainless steel (Col. 5, lines 8 – 10), and an MRI-inert plastics main part (12; Col. 4, lines 29 - 30). The distal part is pinched with the main part (Col. 5, lines 45 – 47). The main part comprises a core comprising an insulant material (12; Col. 4, lines 29 - 30). The main part comprises an artificial material selected from the group of polypropylene, polyethylene, polyetherimides, and polyetheretherketone (12; Col. 4, lines 29 - 30). Additionally, Muni et al. discloses a metallic wire distal part (32) glued to the main part (Col. 5, lines 27 – 30).

6. Claims 1- 4, 7, 8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/42268 to Cordis Corporation.

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In regards to claims 1- 4, 7, 8 and 10, Cordis Corporation discloses an MRI compatible device for guiding catheters (Page 5, lines 7 – 10) having a metallic wire distal part (3) comprising nickel titanium or stainless steel (Page 6, lines 14 – 16), and an MRI-inert plastics main part (7). The main part comprises an artificial material (Page 6, lines 5 – 6). The metallic wire distal part is glued to the main part (Page 6, line 19; Figure 2). Cordis Corporation discloses a core (5) in the center of the main part comprising an insulent material.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,375,629 to Muni et al. as applied to claim 1 above and further in view of U.S. Patent No. 5,492,532 to Ryan et al.

In regards to claim 6, Muni et al. discloses a metallic wire distal part (32) being connected to an MRI-inert plastics main part (12) adhesively, but fails to disclose the connection being shrinkdown plastic tubing. However, Ryan et al. discloses connecting a wire distal part (202) to a main part (158) using shrinkdown plastic tubing (Col. 8, lines 49 – 52). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the connection between the distal part and the main part as disclosed by Muni et al. to include a shrinkdown plastic tubing as taught by Ryan et al. in that Ryan et al. discloses a connection by shrinkdown plastic tubing as being equivalent, and therefore interchangeable, to using an adhesive (Col. 5, lines 28 – 29).

***Response to Arguments***

Applicant's arguments filed 8/8/05 have been fully considered but they are not persuasive. Applicant asserts that Johanson et al. and Muni et al. fail to disclose Applicant's claimed inventions. However, the Examiner disagrees. In regards to Applicant's arguments that Johanson et al. and Muni et al. fail to disclose an MRI compatible device for guiding catheters inside human or animal vessels, the recitation "an MRI compatible device" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Additionally, a recitation with respect to the manner in which an apparatus is intended to be employed does not impose any structural limitation upon the claimed apparatus that differentiates it from a prior art reference disclosing the structural limitations of the claim. *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1947); *In re Yanush*, 477 F.2d 958, 177 USPQ 705 (CCPA 1973); *In re Finsterwalder*, 436 F.2d 1028, 168 USPQ 530 (CCPA 1971); *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 136 USPQ 458 (CCPA 1963); *Ex parte Masham*, 2 USPQ2d 1647 (BbPatApp & Inter 1987). The claims fail to include any structural limitations which set them apart from the prior art. The recitation "main part" is relative. As in the case with Johanson et al., the Examiner has considered the "MRI-inert plastics main part" to include the polymeric tube (30) and plugs located within the tube. These structures in combination form the "main part" of the distal portion of the guide wire as disclosed by Johanson et al.

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***Conclusion***


9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent Application Publication No. 2003/0060731 to Fleischhacker teaches an MRI compatible guidewire having an MRI-inert plastics main part.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
JMLF

  
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